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K123512

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510(k) Summary

Owner's name:	Biodenta Swiss AG
Address:	Tramstrasse 16 9442 Berneck Switzerland
Phone:	+41 71 747 11 11
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Contact person:	Mr. David Eiler, Regulatory Manager
Date summary prepared:	February 18, 2013
Trade / proprietary name:	Biodenta Dental Implant System – Bone Level D 3.0 to 6.0 mm
Common name:	Endosseous dental implant
Device classification name:	implant, endosseous, root-form
Product code:	DZE
Regulation number:	21 CFR 872.3640
Subsequent Product Code:	NHA (Abutment, Implant, Dental, Endosseous; Regulation #: 21 CFR 872.3630)
Legally marketed device to which equivalence is claimed (predicate device):	
1. Company:	Biodenta Swiss AG
Device name:	Biodenta Dental Implant System – Bone Level
510(k) number:	K111003
2. Company:	Nobel Biocare AB
Device name:	Nobel Active 3.0
510(k) number:	K102436

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3. Company:	MIS – Implant Technologies Ltd.
Device name:	Seven Implants; Biocom Implants; Lance Implants
510(k) number:	K103089
4. Company:	Keystone Dental
Device name:	Genesis Implant System
510(k) number:	K101545

Indications for Use:
Biodenta dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures.

Device Description:
The Biodenta Dental Implant System – Bone Level D 3.0 to 6.0 mm is an integrated system of endosseous dental implants, which are designed to support prosthetic devices for partially or fully edentulous patients. The system consists of a variety of dental implants, abutments, prosthetic parts and related surgical instruments. The Bone Level D 3.0 to 6.0 mm implants use the same platforms and abutment connections like the Bone Level implants (K111003) for the diameter 4.1, 4.8, and 6.0 mm implants, and therefore the abutments and prosthetic parts of the Bone Level implants are used. The diameter 3.0 mm implants use the same connection concept in a narrower version. The submission includes:
- Diameter 3.0 mm Implants with Length of: 10, 12, and 14 mm; Platform B0
- Diameter 4.1 and 4.8 mm Implants with Length of: 6.5 mm; Platform B2
- Diameter 6.0 mm Implants with Length of: 6.5, 8, 10, and 12 mm; Platform B2
- Straight abutments (Straight, Temporary, Ball, Locator); B0 platform, Length 10.4 - 14.9 mm, Diameter 3.6 - 4.0 mm
- Healing abutments, closure screws; B0 platform, Height 0.5 - 7.1 mm, Diameter 2.8 - 3.9bmm

Non-clinical Testing Data:
Fatigue testing was conducted according to FDA Guide: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff. The worst case scenario for the Biodenta Dental Implant System - Bone Level D 3.0 to 6.0 mm implants and abutments was tested. The results show that the Biodenta Dental Implant System - Bone Level D 3.0 to 6.0 mm has sufficient mechanical strength for their intended clinical application.

To compare the implant surface area of the Biodenta Dental Implant System - Bone Level D 3.0 to 6.0 mm with the predicate devices an implant surface area analysis has been carried out. All Biodenta Dental Implant System - Bone Level D 3.0 to 6.0 mm implant's surface areas are almost identical or higher than the predicate device surface area. Therefore the surface area is considered to be sufficient.

Clinical Testing:
Non-clinical test data was used to support the decision of safety and effectiveness.

Equivalence to marketed device:
Biodenta Swiss AG demonstrated that, for the purposes of FDA's regulation of medical devices, the Biodenta Dental Implant System - Bone Level D 3.0 to 6.0 mm is substantially equivalent to the predicate devices in intended use, material composition, fundamental scientific technology, principles of operation, and basic design.

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Summary Substantial Equivalence Comparison to predicate devices:

#	Subject Device	Predicate Devices			
Company	Biodenta Swiss AG	Biodenta Swiss AG	Nobel Biocare AB	MIS – Implant Technologies Ltd.	Keystone Dental
Device Name	Biodenta Dental Implant System - Bone Level D 3.0 to 6.0 mm	Biodenta Dental Implant System – Bone Level	Nobel Active 3.0	Seven Implants; Biocom Implants; Lance Implants	Genesis Implant System
510(k) Number	New device	K111003	K102436	K103089	K101545
Intended use	Biodenta dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures.	Biodenta bone level dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures.	The NobelActive 3.0mm implant is indicated for the use in the treatment of missing maxillary lateral incisors of the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patents. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied	MIS dental implants are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function. When a one stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. MIS short implants are to be used only with straight abutment	The Genesis Implant System is intended for use in single-stage or two-stage surgical procedures in all types of bone in partially or fully edentulous mandibles and maxillae. The Genesis Implant System supports single or multiple-unit restorations to re-establish patient chewing function and esthetics. Genesis implants are intended for placement following natural tooth loss or for immediate placement into an extraction socket. Immediate function may be achieved when good primary stability is established and appropriate occlusal loading is applied.
Implant Type	Root-form endosseous dental implant Bone Level Implant	Root-form endosseous dental implant Bone Level Implant	Root-form endosseous dental implant Bone Level Implant	Root-form endosseous dental implant Bone Level Implant	Root-form endosseous dental implant Bone Level Implant
Implant to Abut. Connection	Internal Hexagon	Internal Hexagon	Internal Hexagon	Internal Hexagon	Internal 6 lobe
Implant Diameter (& Length)	D 3.0 mm (L 10 - 14 mm) D 4.1 mm (L 6.5 mm) D 4.8 mm (L 6.5 mm) D 6.0 mm (L 6.5 - 12 mm)	D 3.5 mm (L 8 - 14 mm) D 4.1 mm (L 8 - 14 mm) D 4.8 mm (L 8 - 14 mm)	D 3.0 mm (L 10 - 15 mm)	D 4.0 (L 6 mm) D 5.0 (L 6 mm) D 6.0 (L 6 mm)	D 3.8 mm (L 8.5 - 18 mm) D 4.5 mm (L 8.5 - 18 mm) D 5.5 mm (L 8.5 - 16 mm) D 6.5 mm (L 8.5 - 13 mm)
Abutment Angle	0°, 15°	0°, 15°	0°, 15°	0°, 15°, 20°, 25°	0°, 15°
Implant Material	Titanium Grade 4	Titanium Grade 4	Titanium Grade 4	Ti alloy (Ti 6Al 4V)	Ti alloy (Ti 6Al 4V)
Abutment Material	Ti alloy (Ti 6Al 4V)	Ti alloy (Ti 6Al 4V)	Ti alloy (Ti 6Al 4V)	Ti alloy (Ti 6Al 4V)	Ti alloy (Ti 6Al 4V)
Surface Treatment	Spark Anodization	Spark Anodization	Spark Anodization	Sand blasted and acid etched	Double-acit-etching & Spark Anodization
Sterilization	Delivered Sterile Gamma Irradiation	Delivered Sterile Gamma Irradiation	Delivered Sterile Gamma Irradiation	Delivered Sterile Gamma Irradiation	Delivered Sterile Gamma Irradiation

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 28, 2013

Mr. David Eiler
Regulatory Manager
Biodenta Swiss AG
Tramstrasse 16
Berneck, St. Gallen
Switzerland 9442

Re: K123512
Trade/Device Name: Biodenta Dental Implant System – Bone Level D 3.0 to 6.0 mm
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: February 19, 2013
Received: February 21, 2013

Dear Mr. Eiler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K123512

Device Name: Biodenta Dental Implant System - Bone Level D 3.0 to 6.0 mm

Indications for Use:

Biodenta dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
2013.03.21
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123512